

REMARKS

In response to the Office Action of March 30, 2011, independent claim 1 has been amended in a manner which is believed to address both the objections and rejections raised by the Office. In particular, claim 1 has been amended to remove specific elements recited in the preamble and to place them in the main body of the claim. Other amendments and remarks concerning claim 1 are noted below. No new matter is added.

Claim Objections

At page 2 of the Action, the Office objects to claim 1 on the grounds that the preamble includes limitations that read into the structure of the invention. Although this objection is only now raised even though the preamble is the same as originally filed, applicant has amended the claim to remove the multi-use counter having a display and a dispense action detector from the preamble and has inserted these elements into the main body of the claim.

Claim Rejections – 35 USC §112

At pages 3 and 4 of the Action, claim 1 is rejected under 35 USC §112, second paragraph as being indefinite. The Office states that the limitations “an accommodation on the body” in line 11 of claim 1 is unclear as to what is the accommodation that is referred to be on the body. Other informalities are noted with respect to antecedent basis rejection.

Regarding the phrase “an accommodation on the body”, applicant believes that this rejection may in fact be due to the word “on” and, as a result, claim 1 has been amended to recite that the phrase “an accommodation on the body” has been amended to “an accommodation in the body”. As more fully explained below, it is respectfully submitted that the accommodation as described in the application and as set forth in amended claim 1 is the space within the body for the counter and therefore it is believed that the word “in” adequately describes this relationship and makes the term definite and therefore in compliance with 35 USC §112, second paragraph.

In particular, it is respectfully submitted that the meaning of "accommodation" is clear and is in line with the normal meaning of this term. It is respectfully submitted that the term "accommodation" is generally used to describe a lodging and in the context of claim 1 is used in this way to describe the space in the body for the counter. Thus, referring to Figure 1, the accommodation is shown by reference numeral 17, the space at the end of the source-ending barrel 12 with splines 10. Likewise, in Figure 8, the accommodation is shown by reference numeral 352, the space at the end of barrel 312 having step 350. Both of these accommodations are therefore spaces in the overall body for a counter. If the Examiner is of the opinion that the term "accommodation" in the body is still indefinite in view of the amendment to claim 1, applicant would be willing to amend the term to "receptacle", with support for this amendment found in dependent claim 11.

The Office states that there is lack of antecedent basis for the term "the substance" at line 6 of claim 1. Applicant respectfully disagrees. The preamble reads "a dispenser for dispensing a substance in individual portions" and therefore there is antecedent basis for the term "substance" at line 6 of claim 1.

With respect to the antecedent basis rejection of the limitation "the orifice" at line 9 of claim 1, this portion of the claim has been amended to read "the dispensing orifice" for which there is antecedent basis in the description of the body, namely, "a body having a dispensing orifice".

The antecedent basis rejection for the term "the dispensing action" has been amended to "a dispensing action".

The Office also recites the limitation "the counted" at line 11 of claim 1. It is believed that the Office meant to refer to "the counter" that appears at line 11. This rejection is overcome by the amendment that includes the multi-use counter in the main body of claim 1 and line 11 refers to this multi-use counter.

The Office also rejects the claim with reference to the term "the release" at line 14 of claim 1. To overcome this rejection, claim 1 has been amended to recite "provided with the frangible portion for release of the counter, such that the closure is tamper-evident". The word "the" is therefore deleted. It is therefore respectfully submitted that all of the

rejections under 35 USC §112 have been overcome for the reasons and amendments presented above.

Claim Rejections – 35 USC §103

At pages 4-7 of the Action, claims 1, 3, 4, 7-11, 15, 16, 19, 20, and 23-25 are rejected under 35 USC §103(a) as unpatentable over Dessertine (US patent 5,020,527) in view of Bacon (US patent 7,047,964) further in view of Ma (US patent 6,981,602).

Initially, applicant would like to note that it is respectfully submitted that the cited Bacon patent which issued on May 23, 2006 cannot be relied upon in a 102(b)/103 rejection since its publication date is after the priority date of the present application, which is December 12, 2003. The same argument is applicable with respect to the publication of the application maturing into the '964 patent; namely, US patent application publication 2004/0069301 A1 which was published on April 15, 2004, a date which is subsequent to the priority date of the present application.

However, an underlying international application publication (WO 02/058771) for the international application claiming priority to the same GB applications for which the '964 patent claims priority (GB 0101945.4 and GB 0103856.1) has a publication date of August 1, 2002, whose publication date is more than one year prior to the priority date of the present application and which therefore can be relied upon by the Office in a 102(b)/103 rejection.

It is with reference to this WO 02/058771 publication that the remarks below are presented when reference is made to "Bacon". Please note that the applicant in all of these documents is the same as that of the present application and therefore reliance under a 102(a)/103 or a 102(e)/103 rejection is not permissible.

With respect to claim 1, the Office relies on Dessertine for showing the claimed dispenser except that it argues that Dessertine does not disclose a closure adapted to enclose the counter and does not disclose the closure is tamper-evident comprising a frangible portion. Bacon is relied upon to disclose a medicament dispenser (Figure 3a, 3b) wherein a closure 203 is adapted to co-operate with a portion of the body providing the

accommodation for removably enclosing the counter (105, 106) in the accommodation. Ma is relied upon for disclosing a tamper-evident closure (Figure 4) wherein the frangible portion 20 (Figure 4) is released such that the closure is tamper-evident. The Office further argues that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Dessertine to have included a closure adapted to enclose the counter (counting portions 105,106) as taught by Bacon, because the closure would prevent the apparatus from being contaminated and further argues that it would have been obvious to have modified the teachings of Dessertine in view of Bacon to have a closure provided with a tamper-evident frangible portion as taught by Ma, because it would allow a user a certainty of the apparatus not being tampered with.

For the reasons presented below, it is respectfully submitted that claim 1 is distinguished over Dessertine in view of Bacon and Ma.

As set out in applicant's previous responses, Dessertine discloses a dispenser having a resettable counter and timer unit for monitoring the number of spray doses dispensed by an inhaler. The unit 21 shown in Figure 4 includes an automatic counter chip with a long-life miniature battery which is activated by downward movement of the container 15 against a lever 23 connected to the unit 21. The action of the lever on the unit simultaneously activates the timer which then signals a 'beep' sixty seconds after the lever 23 has been depressed. Once the user has finished, the unit 21 may be simultaneously stopped and reset by depressing the reset button 29.

As acknowledged by the Office in the Action, Dessertine does not disclose a closure adapted to enclose a counter and does not disclose a closure which is tamper-evident.

In the Action, the Office argues that a person of ordinary skill in the art reading Bacon would incorporate the closure disclosed therein into the dispenser of Dessertine. The closure the Office points to in Bacon is mouthpiece cover 203 which is shown in Figures 3a-4d.

This cover in Bacon does not, however, enclose the counter as required by claim 1. Rather as shown in Figures 3a and 4a, the top of the cover sits below the counter when the cover is closed.

This is, in fact, critical to the operation of the counter in Bacon. The cover interacts with piezoelectric film 105. Specifically, when the cover is closed, the film is abutted by the edge of the cover and is held flat. On opening of the cover, the film 105 is free to resume its arched state and in so doing sends a 'wake up' signal to the counter. This is discussed in the first two paragraphs of page 8 of Bacon which are reproduced below:

"A counter 101 is removably mounted on the can 211. It comprises a ring 102 sized to grip the can, yet removable in case of need to refit it to another can. It has an LCD display 103, associated with a counting and timing circuit mounted in the ring. The ring carries two transducing elements. The first is an arched piece of piezo-electric film 105 abutted by the edge of the cover and held flat when the cover is closed. The second is a second piezoelectric film 106 extending through the air inlet 2014, to be abutted by the breath actuation flap 228 when the flap is set to the cocked position in Figure 4(c). This abutment flexes the film from a flat state to which it has a tendency to return.

On opening of the cover, the first film 105 is free to resume its arched state 1051 and in doing so sends a "wake-up" signal to the counter. The flap 228 is set to its cocked state, deflecting the second film 106 to a curved state 1061. This causes it to send a signal to the counter. This is ignored or can be used as an additional wake-up signal or indeed in the possible absence of the film 105, this signal can be the wake-up signal for the counter. On inhalation, two effects combine to flex the second film 106. Firstly, the deflection imposed by the flap is removed. Second inhalation air flexes the film to an oppositely curved state 1062. This flexure causes it to generate a "count" signal causes the counter to decrement by one the count of doses shown on the LCD display 103."

It is therefore essential that the cover in Bacon does not enclose the counter since if it did its edge would not be in the correct position to interact with the piezoelectric film 105 to operate the counter as described.

Accordingly, the applicant respectfully submits that the Office's rejection is fundamentally flawed as the combination of Dessertine and Bacon does not disclose a dispenser having a closure for enclosing a counter as required by claim 1.

Additionally, Bacon does not disclose a dispenser having an enclosure that is a frangible portion such that the closure is tamper-evident. The Office realizes this and cites Ma as disclosing this feature.

Ma is not concerned with dispensers, but rather with containers. The closure comprises a cap 10 with a top portion 12 and a depending annular skirt 14 with a tamper-evidence band 18 connected to lower edge 16 of the annular skirt by a frangible connection 20. The tamper evidencing band 18 includes an inwardly turned retaining rim 24 that extends partially upwardly relative to the container neck and is adapted to engage the locking surface of the container neck. As described at column 7, line 8 *et seq.* of MA, the thin wall construction of the frangible connections allow for a relatively easy breakage of the frangible material when a free edge of the retaining rim engages the locking surface. Thus, when the top is unscrewed connections 20 break.

The Office argues in the Action that a person of ordinary skill in the art would incorporate this tamper evidencing system into the teachings of Dessertine and Bacon. The applicant submits, however, that this does not result in an operative dispenser.

As discussed above, the closure disclosed in Bacon is mouthpiece cover 203. This cover pivots about axis 204 in the body, rather than being screwed on like a cap as in Ma. The opening of the closure in Bacon does not therefore involve the interactions described in Ma that are needed to break its frangible connections.

Moreover, and even more fundamentally, if the mouthpiece cover of Bacon were fitted with a tamper evidencing system with a frangible connection to the body as described in Ma the dispenser would become inoperative. The first time the cover is opened, the frangible connections would break and the cover would be separated from the

body. The opening of the mouthpiece cover is, however, what drives the dispensing mechanism of the dispenser in Bacon. Thus, the opening of the cover lifts the junction member and the stem of the valve towards the can which releases a dose (see page 7 of Bacon). Thus, if the cover were provided on a frangible connection which breaks on opening as disclosed in Ma, the dispenser could only be used once before it would thereafter fail to dispense any doses.

Accordingly, the applicant respectfully submits that the Office's rejection is fundamentally flawed as the combination of Dessertine, Bacon, and Ma does not disclose a dispenser having a closure with a frangible portion that is tamper-evident that works, as required by claim 1.

In summary, the applicant submits that claim 1 is distinguished over the cited prior art at least for the reasons that:

1. A combination of Dessertine and Bacon does not disclose a dispenser having a closure that encloses a counter; and
2. The combination of Dessertine, Bacon, and Ma does not disclose an operative dispenser having a closure with frangible portions such that the closure is tamper-evident.

Since claim 1 is believed to be distinguished over the cited art, it is respectfully submitted that dependent claims 3, 4, 7-11, 15, 16, 19, 20, and 23-25 are also distinguished over the cited art at least in view of their ultimate dependency from an independent claim which is believed to be allowable.

In view of the foregoing, it is therefore respectfully submitted that the present application as amended is in condition for allowance and such action is earnestly solicited.

Applicant's attorney respectfully requests Examiner Kumar to contact the undersigned attorney if there are any remaining questions concerning this response in order to help expedite prosecution of this application.

The Commissioner is hereby authorized to charge to deposit account 23-0442 any fee deficiency required to submit this paper.

Respectfully submitted,

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/Alfred A. Fressola/

Alfred A. Fressola
Attorney for Applicant
Reg. No. 27,550

WARE, FRESSOLA, VAN DER SLUYS
& ADOLPHSON LLP
Bradford Green, Building Five
755 Main Street, P.O. Box 224
Monroe, CT 06468
Telephone: (203) 261-1234
Facsimile: (203) 261-5676
USPTO Customer No. 004955